

Application No. 10/647,068
Docket No. 0101-P02977US1

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Examiner: Philogene, P.

REMARKS

Claims 1-13 are pending in the application, of which claims 1-13 stand rejected.

PROVISIONAL DOUBLE PATENTING REJECTION

Claims 1-13 stand provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-13 of copending Application No. 10/227,161. Since this is only a provisional rejection, no action is required of Applicants in response.

REJECTIONS UNDER 35 U.S.C. 102

Claims 4 and 13 stand rejected under 35 U.S.C. 102(b) as being anticipated by Barbieri (3,874,387). The Office Action states that with “respect to claims 4 and 13, Barbieri disclose a method of treating a bone defect comprising the steps of applying a reduced pressure to the bone defect; ... and, maintaining the reduced pressure until the bone defect has progressed toward a selected stage of healing, the selected stage of healing including formation of neo-osteoid tissue;...” (Citations omitted.) Applicants respectfully disagree with the rejection for at least the reason that Barbieri has nothing to do with a method or device relating to reduced pressure treatment. Rather, Barbieri relates to the opposite – a method and device for treatment with increased pressure.

Specifically, Barbieri relates to a “wound dressing of the occlusive type ... which is placed over and connected to the skin about the wound to seal the wound from the surrounding atmosphere. The member has valves therein which, ... when closed, allow **an increase in fluid pressure about the wound** to prevent further loss of blood out of the wound” (Barbieri, Abstract. Emphasis Added.) Barbieri teaches that “[o]ther dressings ... have the disadvantages of being open to the atmosphere, thus permitting contamination of the wound and allow the wound to continue bleeding.” (Barbieri, column 1, lines 10-17. Emphasis Added.) That is, continued wound bleeding is identified by Barbieri as a problem to be solved. In this regard Barbieri discloses that after cleansing the wound with the valve in the open position, “[t]he valve is then closed. As the wound bleeds, the blood **pressure within the cap will increase** and cause a reduction in the flow of bloodout [sic] of the wound. The pressure in the cap will increase until

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it equals the blood pressure in the body. As the outward flow of blood is stopped, the circulatory flow of blood in the body system past the wound is gradually increased until a normal flow rate is obtained.” (Barbieri, column 1, lines 43-50. Emphasis Added.) Thus, Barbieri discloses increased pressure build up to reduce bleeding of a wound. Barbieri therefore teaches the opposite of reduced pressure at the wound site, which reduced pressure would have the effect of increasing bleeding of a wound in the Barbieri device.

In contrast, Applicants’ invention relates to applying a reduced pressure, and each independent claim recites the feature of “reduced pressure”. Reduced pressure is clearly defined in the specification to be “pressure that is below ambient atmospheric pressure.” (See paragraph [0006], first sentence.) In this regard, claim 4 recites the steps of “(a) applying a reduced pressure to an area of skin over a bone defect; and (b) maintaining the reduced pressure until bone tissue has grown at the defect to provide a selected stage of healing.” Claim 13 recites the steps of “applying a reduced pressure to an area of intact skin above the bone defect; and maintaining said reduced pressure until the bone defect has progressed toward a selected stage of healing, the selected stage of healing including formation of neo-osteoid tissue.” Application of reduced pressure as disclosed and claimed by Applicants is opposite to the disclosure and teaching of Barbieri. Barbieri has nothing to do with applying and maintaining a reduced pressure as claimed by Applicants.

For example, allowing pressure within the cap to increase as a result of the flow of blood out of the wound as taught in Barbieri results in application of an increased pressure to a wound, not a reduced pressure. An increase in pressure, as disclosed in Barbieri, is one that provides a greater pressure relative to ambient, not a decreased pressure relative to ambient. The mere fact that excess fluid may be drained from the wound through open valve 12, as recited at column 3, lines 12-14, is not a disclosure of “applying a reduced pressure...” and “maintaining the/said reduced pressure...” as variously recited in claims 4 and 13. (Emphasis Added.) Indeed, we know that a reduced (i.e., sub-ambient) pressure is not maintained under the cap of Barbieri, for at least the reason that Barbieri indicates that stopping blood flow from the wound is one purpose of the device. Applying and maintaining a reduced pressure would result in an increase of wound bleeding. The inescapable conclusion in that Barbieri, like other wound drainage devices, is merely applying sufficient suction to draw off excess fluids, but does not provide a reduced

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pressure environment about the wound. That is, suction is supplied only in sufficient quantity as required to draw off excess fluids. To conclude otherwise would be inconsistent with the above-quoted language in Barbieri teaching the importance of decreasing bleeding by an increase of pressure under the cap. Indeed, the statements regarding suction appear in the context of the discussion regarding the irrigation of wounds under the Barbieri cap, which occurs in conjunction with “opening both valves.” (Column 3, line 3.) It would make sense that both valves 12 and 12' would be open in order for suction applied to open valve 12 to be more effective at draining fluids.

Furthermore, in addition to teaching the opposite of reduced pressure application maintenance, Barbieri never mentions treating a bone defect. Indeed, the words “bone” and “neo-osteoid” never appear in Barbieri. Hence, the features of “applying a reduced pressure to an area of skin over a bone defect; and (b) maintaining the reduced pressure until bone tissue has grown at the defect to provide a selected stage of healing” as recited in claim 4, are also not disclosed in Barbieri. (Emphasis Added.) Likewise, the features of “applying a reduced pressure to an intact area of skin above a bone defect; and maintaining said reduced pressure until the bone defect has progressed toward a selected stage of healing, the selected stage of healing including formation of neo-osteoid tissue,” as recited in claim 13, are also not disclosed in Barbieri.

For at least the above reasons, Barbieri fails to disclose each and every element recited in independent claims 4 and 13. Therefore, Applicants respectfully request that the rejections of claims 4 and 13 be withdrawn.

REJECTIONS UNDER 35 U.S.C. 103(a)

Claims 1-13 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Barbieri in view of Argenta (5,636,643). The Office Action states that with respect to claims 1-13, “Barbieri disclose a method for administering, applying, facilitating, treating and healing a reduced pressure treatment to a damaged bone tissue”, with which Applicants strongly disagree for the reasons presented above. The Office Action further states that “it is noted that Barbieri did not teach the steps of providing an impermeable cover adapted to enclose the damaged bone tissue and adapted to maintain reduced pressure at the site of the damaged bone tissue; providing

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a seal adapted to seal the cover to tissue surrounding the damaged bone tissue; providing reduced pressure supply means for connection to a source of suction, the reduced pressure supply means cooperating with the cover to supply the reduced pressure beneath the cover,...”, etc. (See Office Action, page 4.) Applicants respectfully submit that the prior art combination is improper for the following reasons.

First, the purpose of the Barbieri device/method is to provide increased pressure on a tissue. Barbieri makes no mention whatsoever of applying and maintaining reduced pressure at a tissue site. **Barbieri teaches a way from reduced pressure.** It is well-established that it is not obvious to modify a reference to do the opposite of what it teaches. (“References Cannot Be Combined Where Reference Teaches Away from Their Combination. It is improper to combine references where the references teach away from their combination. *In re Grasselli*, 713 F.2d 731, 743, 218 USPQ 769, 779 (Fed. Cir. 1983).” MPEP 2145. X. D. 2.). Thus, there is no motivation to modify the device/method of Barbieri to attain reduced pressure as claimed by Applicants.

Second, any proposed modification of Barbieri to turn it into, or operate it as, a reduced pressure device **would render the device/method of Barbieri inoperable for its intended purpose** of preventing bleeding. As already explained, a purpose of the Barbieri device is to provide an increased pressure about the wound site in order to decrease blood flow out of the wound “to prevent further bleeding of the wound and to ensure the flow of blood in the body of the wound.” (Column 1, lines 35-37.) Applying increased pressure is the antithesis of applying reduced pressure to a tissue. It is a well-established principle that it cannot be obvious to modify a reference to render it inoperable for its intended purpose. “If proposed modification would render the prior art invention being modified unsatisfactory for its intended purpose, then there is no suggestion or motivation to make the proposed modification. *In re Gordon*, 733 F.2d 900, 221 USPQ 1125 (Fed. Cir. 1984).” MPEP 2143.01. The use of negative pressure in the Barbieri device would not only defeat the purpose sought after by Barbieri but would make the situation worse. Negative pressure would increase the rate of blood flow out of the wound, not decrease it.

Third, Applicants respectfully point out as stated above that Barbieri relates not to a reduced pressure device/method but to an increased pressure device/method for preventing

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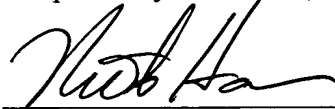
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wound bleeding. Since the present invention is directed to a device/method for applying reduced pressure, Barbieri is non-analogous art relative to the present invention and therefore is not available for making a rejection under 35 U.S.C. 103. See MPEP 2141.01(a): "While Patent Office classification of references and the cross-references in the official search notes are some evidence of 'nonanalogy' or 'analogy' respectively, the court has found 'the similarities and differences in structure and function of the inventions to carry far greater weight.' *In re Ellis*, 476 F.2d 1370, 1372, 177 USPQ 526, 527 (CCPA 1973)." In the instant case, Barbieri is non-analogous art, because it relates to a method for applying increased pressure which is the complete opposite in function of a method for applying reduced pressure as claimed by Applicants.

Hence for at least the above reasons, there is no motivation to modify Barbieri in view of Argenta, and Applicants respectfully submit that the proposed prior art combination of Barbieri with Argenta is improper. Accordingly, Applicants respectfully request that the rejections of claims 1-13 be withdrawn, each of which claims recite "applying" and "maintaining" "a reduced pressure".

In view of the foregoing amendments and remarks, it is believed that the claims in this application are now in condition for allowance. Early and favorable reconsideration is respectfully requested. The Examiner is invited to telephone the undersigned in the event that a telephone interview will advance prosecution of this application.

Respectfully submitted,



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